

Attorney Docket No.: PTQ-0027
Inventors: Van Eyk et al.
Serial No.: 09/115,589
Filing Date: July 15, 1998
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This listing of the claims will replace all prior versions and listings of claims in the application:

Listing of the claims:

Claims 1-79 (canceled)

- 1 Claim ~~80~~ (currently amended): A method for assessing skeletal muscle damage in a subject, comprising detecting the presence or absence or measuring the amount of:
- (a) a peptide fragment of a myofilament protein; or
 - (b) a covalent or non-covalent complex of at least:
 - (i) a peptide fragment of a myofilament protein and an intact myofilament protein; or
 - (ii) two peptide fragments of myofilament proteins,
- in a biological sample obtained from a subject being assessed for skeletal muscle damage, said biological sample being selected from the group consisting of skeletal muscle tissue, a component of skeletal muscle tissue, blood, blood serum and urine, by incubating the biological sample with an antibody or a functional fragment of an antibody antigen specific fragment thereof that specifically binds to the peptide fragment of a myofilament protein under conditions which allow the antibody or functional fragment of the antibody antigen specific fragment thereof to form a complex with the

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(a) peptide fragment of a myofilament protein; or
(b) covalent or non-covalent complex of at least:
(i) a peptide fragment of a myofilament protein
and an intact myofilament protein; or
(ii) two peptide fragments of myofilament
proteins,
and detecting or measuring the formed complex,
wherein said peptide fragment of the myofilament protein or
said peptide fragment of the covalent or non-covalent
complex formation consists of:
a skeletal troponin I peptide fragment, or
a skeletal troponin T peptide fragment,
and wherein the presence or amount of:
(a) the peptide fragment of the myofilament protein; or
(b) the covalent or non-covalent complex of at least:
(i) the peptide fragment of the myofilament
protein and the intact myofilament protein; or
(ii) two peptide fragments of myofilament
proteins,
in the biological sample is associated with skeletal muscle
damage.

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Claim ~~81~~¹ (previously presented): The method of claim
~~80~~¹, wherein the peptide fragment of the myofilament protein
or the covalent or non-covalent complex of at least:

(i) a peptide fragment of a myofilament protein and an intact myofilament protein; or

(ii) two peptide fragments of myofilament proteins consists of a covalent complex.

3 Claim ~~82~~ (previously presented): The method of claim ~~80~~
wherein the presence of at least two different peptide
fragments of myofilament proteins or covalent or non-
covalent complexes is detected.

4 Claim ~~23~~ (previously presented): The method of claim
1 ~~20~~ wherein the amounts of at least two different peptide
 fragments of myofilament proteins or covalent or non-
 covalent complexes are measured and the measured amounts are
 compared as an indication of the extent of skeletal muscle
 damage in the subject.

5 Claim ~~84~~ (previously presented): The method of claim ~~80~~
wherein the ratio of at least two different peptide
fragments of myofilament proteins or covalent or non-
covalent complexes is assessed as an indication of the
extent of skeletal muscle damage in the subject.

Claim 85-86 (canceled)

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6 Claim ~~87~~ (previously presented): The method of claim ~~80~~¹, wherein the complex is detected or measured by assaying for the presence of a label.

7 Claim ~~88~~ (previously presented): The method of claim ~~80~~¹, wherein the antibody or functional fragment of the antibody is labeled with an enzyme which is detected by measuring enzymatic activity associated therewith.

8 Claim ~~89~~ (previously presented): The method of claim ~~88~~⁷, wherein the enzyme is selected from the group consisting of alkaline phosphatase, horseradish peroxidase, luciferase, beta-galactosidase, lysozyme, glucose-6-phosphate dehydrogenase, lactate dehydrogenase, and urease.

9 Claim ~~90~~ (previously presented): The method of claim ~~80~~¹, wherein the antibody or a functional fragment of an antibody is immobilized on a solid phase.

10 Claim ~~91~~ (previously presented): The method of claim ~~90~~⁹, wherein the solid phase is a plastic surface.

11 Claim ~~92~~ (previously presented): The method of claim ~~80~~¹ wherein the skeletal muscle damage is reversible.

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12 Claim ~~93~~ (previously presented): The method of claim ~~92~~¹¹
wherein the skeletal muscle damage is due to at least one
condition selected from the group consisting of hypoxia,
hypoxemia, ischemia, fatigue and reperfusion.

13 Claim ~~94~~ (previously presented): The method of claim ~~90~~¹
wherein the skeletal muscle damage is irreversible.

14 Claim ~~95~~ (previously presented): The method of claim ~~94~~¹³
wherein the skeletal muscle damage is due to at least one
condition selected from the group consisting of hypoxia,
hypoxemia, ischemia, and reperfusion.

Claim 96 (canceled)

15 Claim ~~97~~ (currently amended): A method for assessing
skeletal muscle damage in a subject, comprising detecting
the presence or absence or measuring amounts of at least two
different:

- (a) peptide fragments of a myofilament protein
- (b) covalent or non-covalent complexes of at least:
 - (i) a peptide fragment of a myofilament protein
and an intact myofilament protein; or
 - (ii) two peptide fragments of a myofilament
protein,

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in a biological sample obtained from a subject being assessed for muscle damage, said biological sample being selected from the group consisting of skeletal muscle tissue, a component of skeletal muscle tissue, blood, blood serum and urine, by incubating the biological sample with an antibody or ~~a functional fragment of an antibody~~ antigen specific fragment thereof that specifically binds to the peptide fragment of a myofilament protein, under conditions which allow the antibody or ~~functional fragment of the antibody~~ antigen specific fragment thereof to form a complex with the

(a) peptide fragment of a myofilament protein; or
(b) covalent or non-covalent complex of at least:
(i) a peptide fragment of a myofilament protein and an intact myofilament protein; or
(ii) two peptide fragments of myofilament proteins,
and detecting or measuring the formed complex,
wherein said peptide fragments of the myofilament protein or said peptide fragments of the covalent or non-covalent complexes consist of:

skeletal troponin I peptide fragments, or
skeletal troponin T peptide fragments,
wherein the presence or amount of the:

(a) peptide fragments of the myofilament protein; or

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(b) covalent or non-covalent complexes of at least:

(i) the peptide fragment of the myofilament protein and the intact myofilament protein; or

(ii) two peptide fragments of the myofilament protein,

in the biological sample are associated with muscle damage, and

wherein the

(a) peptide fragments of the myofilament protein; or

(b) covalent or non-covalent complexes of at least:

(i) the peptide fragment of the myofilament protein and the intact myofilament protein; or

(ii) two peptide fragments of the myofilament protein,

are from the same myofilament protein.

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16 Claim ~~98~~ (previously presented): The method of claim ~~97~~
wherein the ratio of the

(a) peptide fragments of the myofilament protein; or

(b) covalent or non-covalent complexes of at least:

(i) the peptide fragment of the myofilament protein and the intact myofilament protein; or

(ii) two peptide fragments of the myofilament protein,

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from the same myofilament protein is assessed as an indication of the extent of the muscle damage in the subject.

Claim 99-102 (canceled)

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17 Claim ~~103~~ (new): The method of claim ~~80~~ wherein said biological sample is skeletal muscle tissue.
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18 Claim ~~104~~ (new): The method of claim ~~80~~ wherein said biological sample is a component of skeletal muscle tissue.
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19 Claim ~~105~~ (new): The method of claim ~~80~~ wherein said biological sample is blood.
- 1
20 Claim ~~106~~ (new): The method of claim ~~80~~ wherein said biological sample is blood serum.
- 1
21 Claim ~~107~~ (new): The method of claim ~~80~~ wherein said biological sample is urine.
- 15
22 Claim ~~108~~ (new): The method of claim ~~87~~ wherein said biological sample is skeletal muscle tissue.

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23 Claim ~~109~~ (new): The method of claim ~~97~~ wherein said biological sample is a component of skeletal muscle tissue.

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24 Claim ~~110~~ (new): The method of claim ~~97~~ wherein said biological sample is blood.

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25 Claim ~~111~~ (new): The method of claim ~~97~~ wherein said biological sample is blood serum.

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26 Claim ~~112~~ (new): The method of claim ~~97~~ wherein said biological sample is urine.